THE UNIVERSITY OF MELBOURNE

Faculty of Medicine, Dentistry and Health Sciences

MISCH *Hub*

Methods and Implementation Support for Clinical and Health Research

Biostatistics and Clinical Epidemiology *Node*

Biostatistics and clinical epidemiology are critical to ensure the success of clinical and health research studies. Biostatistical as well as epidemiological skills are required throughout all stages of the design, conduct and analysis of a research study. An essential component is the sound application of appropriate statistical methods. This is complemented by knowledge and skills in the design of both clinical trials and observational research studies (see Figure 1), as well as an ability to appropriately report and interpret data from clinical and health research studies. The Biostatistics and Clinical Epidemiology Node offers this expertise to health researchers affiliated with the University of Melbourne.

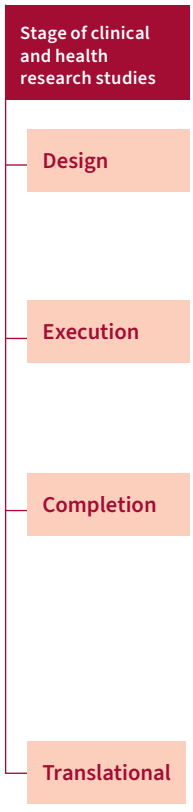

Figure 1: Biostatistics services provided at each stage of a clinical or health research study

What does this node offer?

Our **MISCH biostatisticians/epidemiologists** provide expertise in the following:

Design stage - Development of the research question(s), selection of appropriate study design, sample size calculations, writing of grant application, study protocol development, ethics applications, statistical analysis plan creation.

Execution stage – Review data collection forms and database design, generate randomisation lists, quality control of data collection procedures (including ethical handling of data), contribution to data safety monitoring committee reports.

Completion stage – Support data cleaning and reproducible data processing, conduct statistical analysis (especially where requiring skills to perform complex analyses), preparation of written summaries (including graphical and tabular displays) of statistical analyses for publication in health-related journals or professional reports, including sound interpretation of statistical findings.

Translational stage - Interpretation and effective communication of research findings, leading to the development of policies and guidelines.

Frequently Asked Questions

What can I expect from my Biostatistics consultation?

During your initial consultation, a member of our Biostatistics and Clinical Epidemiology node will work with you to identify the statistical support required for the aims of your study. This may involve the development or refinement of the research question(s). We ask about the intended biostatistical support required for your research study, your timelines and, importantly, your budget for biostatistics. We will then complete a collaboration agreement outlining how our node will be involved in the study, including co-authorship on research articles if appropriate, which we will ask you to sign.

Can I just be trained to do the analysis myself?

We do offer training in introductory statistical methods and also recommend biostatistics courses delivered by other groups (see our website).

These courses provide training in performing basic statistical analyses using statistical packages (e.g., Stata, R) and examples of how findings can be interpreted and presented. However, importantly, the analysis for clinical trials should be performed by an independent biostatistician. In addition, many observational studies involve sophisticated statistical methods and therefore require the expertise of a biostatistician.

Why do we name one of the MISCH members as an investigator on grant applications?

Grant assessors for NHMRC, MRFF and other funding schemes evaluate whether the team of investigators have the requisite qualifications to deliver the project. For clinical trials, cohorts and other quantitative research studies, they will expect to see a biostatistician or epidemiologist included in the investigator team. As an investigator they will critically review the grant application, including formulation of the research question and selection of study design, and draft the sections on sample size, randomisation (for a trial) and statistical analysis.

Why do I need to include a budget in my grant application for biostatistics support?

As biostatisticians provide statistical support to all stages of a research study (for example see Figure 1), budgeting this within your grant proposal is necessary. We can advise regarding the best package for your project in our initial consultation.

Do MISCH have to be included as co-author/s?

Where intellectual contributions are made by MISCH experts, co- authorship follows the University of Melbourne publication policy (MPF1181). Depending on the contributions to a project, MISCH experts may be considered collaborators at the same level as other academic colleagues who contribute intellectually and receive funding for work on a project

Contact us

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